DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed June 29, 2009. Claims 1, 4 – 7, 15, 23, 25, and 27 - 28 are amended. claims 2 – 3, 8 – 14, 18 – 19, 21 – 22, 24, 26, and 29 are canceled (claim 20 was previously canceled). Claims 1, 4 - 7, 15 – 17, 23, 25, 27 – 28, and 30 – 31 are presented for examination.

Claim Objections

2. The objections to claims 18 and 24 – 28 are hereby withdrawn based upon the amendment submitted June 29, 2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 (d) and (e) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (d) recites "excluding from the medication specific data names of all physical conditions associated with said significant contra-indications" and claim 1 (e) recites "generating names of all remaining physical conditions associated with the patient in the medication specific data"; It appears the Applicant is excluding all significant interactions, thus the remaining interactions are insignificant. When you move forward to step (g) which recites "outputting from the data processing system to a remote user location the names of the remaining physical conditions associated with the patient in the medication specific data, the significant side effects, the significant drug-drug interactions, and the therapeutic class" the significant interactions have been excluded, thus you are outputting the insignificant interactions.

5. The 35 U.S.C. 112, second paragraph rejection of claim 3 is hereby withdrawn based upon the amendment submitted June 29, 2009.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1 and 4 - 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilski et al*, 88 USPQ 2d 1385 CAFC (2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). For instance, the method steps recited in the body of claim 1 are not tied to a particular machine. Dependent claims 4 - 7 have similar deficiencies as noted above with regard to claim 1 and therefore are rejected for substantially the same reason.

8. The 35 U.S.C. 112, second paragraph rejections of claims 23 - 30 are hereby withdrawn based upon the amendment submitted June 29, 2009.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 6, 8 – 24, and 26 - 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton (U.S. Publication No. 2003/0204415 A1) in view of Ghouri (U.S. Publication No. 2004/0162835 A1), and further in view of Fabrick et al., herein after Fabrick (U.S. Publication No. 2004/0088317 A1).

In regard to claim 6 (Currently Amended), Knowlton and Ghouri teach the method of claim 1.

Fabrick further teaches a method wherein: in step (b) the medication specific data includes information indicative of patient usage of prescribed medications (Figure 1 and paragraph [0030]); and in step (f) the consequential information includes information regarding the indicated patient usage of prescribed medications (Figure 1; paragraphs [0025], [0027], and [0030]) where information regarding a patient is stored in a database, including side effect information.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein in step (b) the medication specific data includes information indicative of patient usage of prescribed medications; and in step (f) the consequential information includes information regarding the indicated patient usage of prescribed medications as aught by Fabrick, within the method of Knowlton and Ghouri, with the motivation of providing a medical professional customized information regarding a patient, such as medical condition (paragraph [0065]).

In regard to claim 15 (Currently Amended), Knowlton teaches a method of generating a medical profile for a patient, comprising:

(a) storing in a data processing system patient medication information representing one or more medications associated with a patient, the patient medication information including medication distribution information obtained from a health care provider (Figure 10c: paragraphs [0043], [0045], [0053], [0067], and [0078]);

(d) facilitating the display of the patient medication information and profile information including only said severe and moderate drug-drug interactions which are probable to a user by outputting said information from the data processing system to a user interface (paragraphs [0043], [0047], and [0124]); and

(e) controlling the display of said patient medication information and profile information by providing an identification code and pass code to the user that must be entered for the user to gain access to the user interface (paragraph [0042], [0062], [0063], [0103], and [0122]).

Ghouri teaches a method comprising: (b) comparing within the data processing system the patient medication information to a database to identify profile information said profile information including severe, moderate and mild drug-drug interactions which are probable (paragraphs [0069], [0070], [0071], and [0113]).

Fabrick teaches a method wherein mild drug-drug interactions are automatically excluded from the profile information (paragraph [0039]).

The motivation to combine the teachings of Knowlton, Ghouri, and Fabrick is discussed in the rejection of claim 6, and incorporated herein.

In regard to claim 16 (Currently Amended), Knowlton, Ghouri, and Fabrick teach the method of claim 15. Knowlton teaches a method wherein step (a) further comprises entering into the data processing system patient medication information representing one or more medications associated with a patient (paragraphs [0053], [0067], and [0078]), the information including medication distribution information obtained from a plurality of health care providers (paragraphs [0042] and [0057]) where the caregivers typically include, but are not limited to, physicians, nurses, and pharmacists.

In regard to claim 17 (Original), Knowlton, Ghouri, and Fabrick teach the method of claim 16. Knowlton teaches a method wherein in step (b) the profile information includes a severe side effect of the medication (paragraph [0058]) where a profile database is comprised of the effects of medication which is equated to side effect data.

Knowlton and Fabrick fail to teach a method where the profile information includes a severe drug-drug interaction of the medication and a therapeutic class of the medication.

Ghouri teaches a method where the profile information includes a severe drug-drug interaction of the medication and a therapeutic class of the medication (paragraphs [0032] and [0113]).

The motivation to combine the teachings of Knowlton, Ghouri, and Fabrick is discussed in the rejection of claim 11, and incorporated herein.

In regard to claim 23 (Currently Amended), Knowlton teaches a medical profile generating system, comprising:

a data processing system (paragraph [0044] and [0049]);

an input module (paragraph [0064] where Knowlton discloses input programs which is equated to an input module as both are software regarding the input of data), embodied on a computer readable medium, wherein medication information comprising names of a plurality of medications prescribed for each of a plurality of patients is input into the data processing system (paragraphs [0053], [0067], and [0078]);

a patient profile database within the data processing system including for each of the plurality of patients a patient profile (Figure 10G; paragraphs [0095] and [0116] where the patient profile is the medical history of a patient), each patient profile including

medication specific data for the plurality of medications which have been prescribed for the patient (Figure 10G; paragraphs [0095] and [0116]);

a secured access to the patient profile database, requiring entry of patient, identification information and user password information in order for a user to gain access to the identified patient's profile (paragraphs [0062], [0063], [0103], and [0122]).

Ghouri teaches a medical profile generating system comprising: consequential information generated by the data processing system from the medication specific data, the consequential information including identification of drug-drug interactions of the prescribed medications, side effects of the medications, and disease drug contra indications having a severity classification of moderate and/or severe (paragraphs [0032], [0035], and [0059]).

Fabrick teaches a system wherein any identified drug-drug interactions, side effects and disease drug contra indications having a severity classification of less than moderate are automatically suppressed by the data processing system such that the consequential information does not include the suppressed interactions (paragraph [0039]).

The motivation to combine the teachings of Knowlton, Ghouri, and Fabrick is discussed in the rejection of claim 6, and incorporated herein.

In regard to claim 27 (Original), Knowlton, Ghouri, and Fabrick teach the system of claim 23.

Fabrick teaches a system wherein: the medication specific data includes information indicative of actual patient usage of the prescribed medications (Figure 1 and paragraph [0030]); and the consequential information includes information regarding the indicated actual patient usage of prescribed medications (Figure 1; paragraphs [0025], [0027], and [0030]).

The motivation to combine the teachings of Knowlton, Ghouri, and Fabrick is discussed in the rejection of claim 6, and incorporated herein.

In regard to claim 28 (Original), Knowlton, Ghouri, and Fabrick teach the system of claim 23. Knowlton teaches a system wherein the secured access permits a selected class of users to access less than all of the consequential information in the patient profile (paragraphs [0042], [0062], [0063], and [0103]) where a level of access is granted based upon a caregivers function (i.e. physician versus pharmacist).

In regard to claim 30 (Previously presented), Knowlton, Ghouri, and Fabrick teach the method of claim 15. Knowlton teaches a method further comprising: analyzing the patient medication information to extract at least one disease treated by medications described in the patient medication information (Figures 7A through 7E).

Knowlton fails to teach a method identifying disease/drug contra-indications according to the patient medication information and the at least one disease.

Ghouri teaches a method identifying disease/drug contra-indications according to the patient medication information and the at least one disease (paragraph [0106]).

The motivation to combine the teachings of Knowlton, Ghouri, and Fabrick is discussed in the rejection of claim 11, and incorporated herein.

In regard to claim 31 (Previously presented), Knowlton, Ghouri, and Fabrick teach the method of 23.

Ghouri teaches the method wherein the consequential information further includes any disease/drug contra-indications as identified by comparing at least one disease, treated by one or more of the plurality of medications, to each of the plurality of medications (paragraph [0106]).

The motivation to combine the teachings of Knowlton, Ghouri, and Fabrick is discussed in the rejection of claim 11, and incorporated herein.

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton, Ghouri, and Fabrick as applied to claim 23 above, and further in view of Mayaud (U.S. Patent Number 7,072,840).

In regard to claim 25 (Original), Knowlton, Ghouri, and Fabrick teach the system of claim 23.

Mayaud teaches a system wherein the consequential information further includes identification of multiple medications in a therapeutic class as a possible indication of duplicative medication (column 28, lines 31 – 41)

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the consequential information further includes identification of multiple medications in a therapeutic class as a possible indication of duplicative medication as taught by Mayaud, within the system of Knowlton, Ghouri, and Fabrick, with the motivation of providing a comprehensive computerized method of assisting a physician in the selection of pharmaceutical medications to minimize adverse reactions (column 14, lines 29 – 49).

Response to Arguments

13. Applicant's arguments filed June 29, 2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filled June 29, 2009. In response to Applicant's argument, it is respectfully submitted that the amended limitations were not in the previously pending claims. As such, the amended claims are addressed in the above office action.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626